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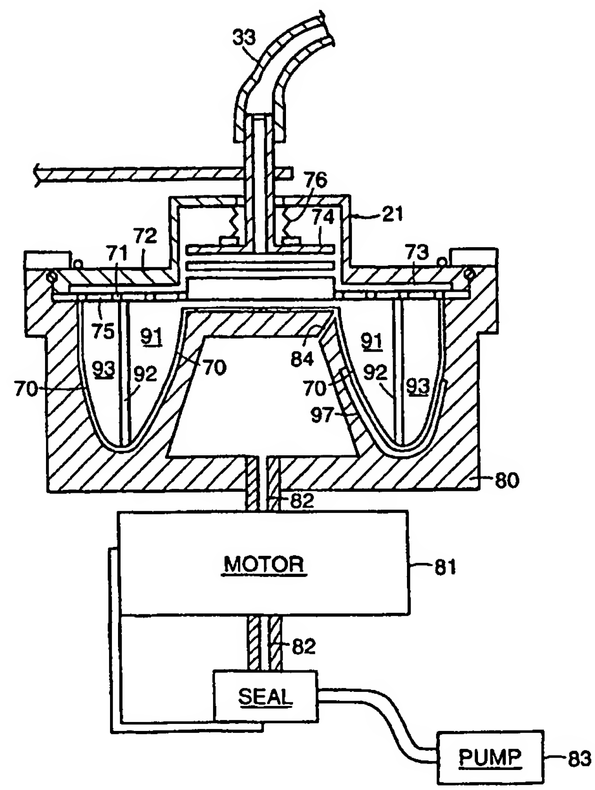
(54) Title: SYSTEM AND METHOD FOR COLLECTING PLATELETS AND OTHER BLOOD COMPONENTS

(57) Abstract

A system for collecting, from whole blood, platelets suspended in plasma. By centrifuging the blood at a high enough rotational speed, the platelets (92) are separated from the plasma (91) and the red blood cells (93). In a preferred embodiment, some of the plasma (91) is removed while the centrifuge is being spun to keep the platelets (92) separated from the plasma (91). Then, the speed of rotation is altered so as to cause the platelets (92) to mix with the remaining plasma (91). The platelets (92) can then be collected with the remaining plasma (91).



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# SYSTEM AND METHOD FOR COLLECTING PLATELETS AND OTHER BLOOD COMPONENTS

## Technical Field

This invention generally relates to systems and methods for processing blood and other biological fluids.

## Background Art

Fig. 1 shows a typical disposable bag set used in the prior art to collect platelets from whole blood. The set includes a needle **10** or cannula, which is inserted into a vein of a donor. The needle **10** is connected to the tube **11**, which in turn is connected to collection bag **12**, so as to allow whole blood to flow from the donor through the needle **10** and the tube **11** into collection bag **12**. The collection bag **12** contains anticoagulant. After the desired amount of blood has been collected into collection bag **12**, the needle **10** is removed from the donor, and tube **11** is cut and heat sealed. The remainder of the bag set is then brought to a centrifuge, which spins the bag set so that the blood in collection bag **12** separates into platelet-rich plasma and red blood cells. Typically, the centrifuge is not located at the point where the blood donation takes place.

After the blood has separated into platelet-rich plasma and red blood cells (RBCs), the bag set is removed from the centrifuge. The platelet-rich plasma is urged from collection bag **12** through tube **13** into platelet-storage bag **14**. The tube **13** leading to the platelet- and plasma-storage bags **14, 15** is then cut and heat sealed. Storage-solution bag **16** holds RBC-storage solution. After the platelet-rich plasma has been urged into the platelet-storage bag **14**, the RBC-storage solution is urged from the storage-solution bag **16** into the collection bag **12**. The tube **41** connecting the collection and storage-solution bags **12, 16** is then cut and heat sealed.

At this stage, the bag set has been divided into two portions: (i) the first portion consists of the collection bag **12**, which now holds primarily red blood cells (along with storage solution), filter **17**, RBC-storage bag **18**, and the tubing **19** that connects these components, and (ii) the second portion consists of the platelet-storage bag **14**, which now holds platelet-rich plasma, and the plasma-storage bag **15** and the tubing that connects these two components.

The first portion may be hung, so that gravity causes the RBC component to pass from the collection bag **12** through the filter **17** to RBC-storage bag **18**. The filter **17** removes white blood cells (WBCs) from the red blood cells. After the red blood cells (and storage solution) pass into the RBC-storage bag **18**, tube **19** is cut and heat sealed.

To collect platelets, the second portion is centrifuged at a high rotational speed in order to separate the platelets from the plasma. After the platelets have been separated from the plasma, some of the plasma is urged from the platelet-storage bag **14** into the plasma-storage bag **15**. Typically, 50 mls of plasma are left with the platelets in the platelet-storage bag **14**. After the desired amount of plasma has been removed from the platelet-storage bag **14** to the plasma-storage bag **15**, the tube connecting these two bags is cut and heat sealed. Thus, at the end of the procedure, the platelet-storage bag **14** holds platelets in about 50ml of plasma, the plasma-storage bag **15** holds platelet-poor plasma, and the RBC-storage bag **18**, of course, holds red blood cells.

This prior-art process of collecting and separating blood components involves many steps and frequent human intervention. The arrangement of the prior-art bag set does not permit the process to be easily automated.

## Summary of the Invention

The present invention is directed to systems and methods for collecting, from whole blood, platelets suspended in plasma. By centrifuging the blood at a high enough rotational speed, the platelets are separated from the plasma and the red blood cells. In a preferred embodiment, some of the plasma is removed

while the centrifuge is being spun to keep the platelets separated from the plasma. Then, the speed of rotation is altered so as to cause the platelets to mix with the remaining plasma. The platelets can then be collected with the remaining plasma.

A system that may be used for carrying out the invention includes a centrifuge rotor, a flow-control arrangement and a spinner. The flow-control arrangement introduces whole blood into the centrifuge rotor and removes blood components from the centrifuge rotor. A controller causes the spinner to rotate at two different speeds: The rotor is spun at a first speed so as to separate the blood into a first component, a second component and a third component. The first component is primarily plasma. The second component is located, while the rotor is being spun, outside of the first component and is primarily red blood cells. The third component is located, while the rotor is being spun, between the first and second components and includes platelets. The controller causes the rotor's speed of rotation to be altered so as to cause the third component to mix with the first component. The controller also causes the flow-control arrangement to remove from the rotor a portion of the plasma containing platelets.

As noted above, in a preferred embodiment, the controller causes the flow-control arrangement to remove some of the first component (the plasma) before the third component (comprising the platelets) is mixed with the first component. The system also preferably includes a plasma-volume determination sensor in communication with the controller; the plasma-volume determination sensor determines the volume of the first component in the rotor. The controller may thus remove a portion of the first component based on the determined volume of the first component.

Brief Description of the Drawings

FIG. 1 shows a disposable set that may be used in a prior-art system for collecting platelets from whole blood.

FIG. 2 shows a cross-sectional view of a variable-volume rotor mounted in a chuck that spins the rotor and causes the rotor's volume to change.

FIG. 3 shows a disposable set using a variable-volume rotor, such as the one in FIG. 2.

FIG. 4 shows a control unit holding the disposable of FIG. 3.

## Description of Specific Embodiments

A method of collecting platelets is described in connection with FIG. 2. FIG. 2 shows a cross-section of a rotor **21** mounted in a chuck **80**, which is located in the control unit and which holds the rotor **21**. This rotor **21** may be any one of a variety of designs, but preferably the rotor has a variable total volume, such as the rotors shown and described in U.S. Patent No. 5,733,253 (which is incorporated herein by reference). (The rotor shown in FIG. 2 is similar to the rotor shown in Figs. 1-4 of U.S. Patent No. 5,733,253, but it will be appreciated that other designs, such as other designs shown in U.S. Patent No. 5,733,253, may be used instead.) A motor **81** causes the chuck **80** and the rotor **21** to spin. The control unit also includes a pump **83**, which is connected through the cannulated axis **82** of the motor **81** to the interior of the chuck **80**. The rotor **21** has an elastic diaphragm **70**, which defines the interior volume of the rotor **21**. Upper boundary wall **72** also defines the interior volume of the rotor **21**. The position of the diaphragm **70** determines the volume of the rotor, and the position of the diaphragm **70** may be controlled by controlling, by means of the pump **83**, the pressure of the gas in the interior of the chuck **80**. The interior of the chuck **80** includes one or more apertures **84** to permit the gas to come into fluid communication with the diaphragm **70**. The rotor **21** may also include a interior wall **75** with perforations **71**. The boundary wall **72** and the interior wall **75** form a passage **73**, through which blood and blood

components may flow to and from the rotor's non-rotating portion **74** and the tubing **33** attached to the rest of the disposable set. A rotary seal **76** provides a seal between the rotating and non-rotating portions of the rotor **21**. In lieu of the perforated interior wall **75**, channels may be located on the interior surface of the boundary wall **72** to provide fluid communication between the rotor's non-rotating portion **74** and the outer radius of the rotor's interior (as shown in Figures 41 and 42 of above-referenced U.S. Patent No. 5,733,253).

FIG. 2 shows the rotor **21** at its maximum volume, with the diaphragm **70** stretched as far as the chuck **80** permits it to be stretched. The rotor **21** is spun sufficiently fast by the chuck **80** and the motor **81** to cause the blood to be separated into red blood cells **93**, platelets **92** and plasma **91**. Since, of these three blood components, the RBC component **93** of the blood has the greatest specific gravity, the RBC component is the furthest from the rotor's axis of rotation. The plasma component **91** has the lightest specific gravity, and therefore the plasma component is the closest to the axis of rotation. The platelet component **92**, having an intermediate specific gravity, forms a thin layer between the plasma and RBC components.

In order to collect the platelets, it is preferable first to collect all but about 50 milliliters of the plasma. The remaining 50 mls of plasma will be used to store the platelets, as the standard practice in the industry is to store a unit of platelets in 50 mls of plasma. The plasma **91** is collected (i.e., urged through fixed portion **74** to tube **33**) by continuing to spin the rotor **21** and using the pump **83** to increase the pressure against the diaphragm **70**, and/or by slowing the revolutions of the rotor **21**. The rotor **21** should preferably continue to be spun quickly and smoothly enough to keep the platelets **92** in a separate layer.

Once all but 50 mls of plasma **91** has been collected, the platelets **92** may be mixed with the remaining plasma by sharply changing the speed of rotation of the rotor **21**. It has been found that, by sharply changing the rotor's speed of rotation, the platelets will mix with the neighboring plasma. Because the red blood cells have a much heavier specific gravity, the red blood cells tend to

remain in their separate layer. Of course, the rotor's speed must not be altered so radically and quickly as to cause the red blood cells as well to mix with the other components. Alternatively, the speed of rotation may be slowed sufficiently--although not necessarily sharply--so that the platelets mix with the plasma but the red blood cells remain separate. Once the platelets are mixed with the remaining plasma, additional pressure may be created by the pump **83** to push the diaphragm **70** further outward and force the platelets, now suspended in plasma, out of the rotor into tube **33**. The red blood cells may then be collected. Each of the components, platelets suspended in plasma, platelet-poor plasma, and the red blood cells should be directed to a separate container. Alternatively, one or both of the platelet-poor plasma and the red blood cells may be returned to the donor.

FIG. 3 shows a disposable set that may be used in the platelet-collection process just described. The disposable set includes the rotor **21**, a plasma-storage container **24**, a platelet-storage container **99**, a RBC-storage container **28**, a filter **17** for removing white blood cells from the red blood cells, a cannula **10** (or other means for permitting whole blood to enter the disposable set), and tubing **33** connecting these components. The plasma-storage container **24** may contain anticoagulant, which may be introduced into the whole blood as it is being drawn through the needle **10** to the rotor **21**. The platelet-storage container **99** may contain platelet-storage solution, and the RBC-storage container **28** may contain RBC preservative. After the plasma and the platelets have been removed from the rotor **21**, the RBC preservative may be urged from the RBC-storage container **28** into the rotor **21**, where the RBC preservative is mixed with the red blood cells remaining in the rotor **21**. The red blood cells and the preservative may then be urged from the rotor **21** through the filter **17** into the RBC-storage container **28**, in the manner described in concurrently filed application, serial no. __/_______, for a "System and Method for Separating Blood Components," bearing attorney docket number 1611/112 and listing Headley and Powers as inventors. (This application is incorporated herein by

reference.) Alternatively, the present invention may be used with the system and process described in concurrently filed application, serial no. __/______, for a "System and Method for Red-Blood-Cell Apheresis," bearing attorney docket number 1611/119 and listing James Cianci as the inventor. (This application is also incorporated herein by reference.)

FIG. 4 shows the disposable set of FIG. 3 mounted in a control unit **20**. The control unit **20** includes a flow-control arrangement for controlling and/or causing flow between the needle **10**, the rotor **21** and the storage containers **24**, **99**, **28**. The flow-control arrangement may include valves **22**, **23**, **98**, **27**, which control the flow through the various branches of the tubing. Alternatively, a single valving cassette may be used to control the flow through the various branches of the tubing. By varying the pressure against the rotor's diaphragm (item **70** in FIG. 9), and by varying the speed that the rotor is spun **21**, fluid may be urged into or out of the rotor from and to the needle **10** or the storage containers **24**, **99**, **28**. For instance, applying a vacuum on the rotor's diaphragm while valve **22** is open helps draw blood from the donor into the rotor **21**. In addition to or in lieu of changing the pressure against the rotor's diaphragm, the control unit may be provided with independent pumping mechanisms (such as a peristaltic pump) that act on the tubing (or on a valving cassette) to force fluid through the tubing in the desired direction.

In order to determine how much plasma should be removed in order to leave only 50 mls of plasma, in which the platelets are to be suspended, the control unit may be provided with an arrangement for determining the volume of the red blood cells. One means of determining the volume of the red blood cells is to provide an array **97** of optical sensors (shown in FIG. 2) in the chuck **80** to determine the radius of the inner boundary of the red blood cells **93** when the blood has been centrifuged into different components. (If the boundary wall **72** is translucent, the array may be mounted above the rotor **21** instead of below it.) The control unit **20** may then calculate the volume of the red blood cells based on the location of this boundary when the rotor is filled with, say, one unit of

blood. Using this volume information, the control unit may determine approximately the weight of the red blood cells in the rotor, based on the specific gravity of red blood cells.

By weighing the chuck/rotor combination before and after the whole blood was introduced into the rotor, the control unit may determine the weight of all the blood components in the rotor when the rotor is filled. By subtracting the weight of the red blood cells from the total weight of all the blood components in the rotor, the control unit may determine approximately the weight of the plasma in the rotor, and how much of it should be removed in order to leave approximately 50 mls of plasma in the rotor. By weighing the chuck/rotor combination as platelet-poor plasma is being urged from the rotor, or alternatively by weighing the container **24** that holds the plasma as it leaves the rotor, the control unit can stop removing plasma when the correct amount of plasma has been removed. The platelet-poor plasma is preferably directed to the plasma-storage container **24**.

At that point, there should be approximately 50 mls of plasma left in the rotor, as well as all the platelets and all the red blood cells. The speed of the rotor may then be changed rapidly, in order to cause the platelets **92** to become mixed in the approximately 50 mls of the plasma remaining. The platelet/plasma combination is then urged from the rotor and sent to the platelet-storage container **99**. Another optical sensor **96**, mounted on the outlet tube **33** senses when the red blood cells start emerging from the rotor. (See FIG. 4.) When the red blood cells are detected, flow to the platelet-collection container **99** is stopped, and the red blood cells may be directed through filter **17** to a RBC-collection container **28**.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A system of collecting a fluid component of intermediate specific gravity, mixed with a fluid component of lighter specific gravity, the system comprising:

a centrifuge rotor;

a flow-control arrangement which introduces whole fluid into the centrifuge rotor and removes fluid components from the centrifuge rotor;

a spinner which rotates the rotor at more than one speed;

a controller for causing the spinner to rotate the rotor at a first speed so as to separate the fluid into a first component, a second component and a third component, wherein the first component has the lightest specific gravity, wherein the second component is located, while the rotor is being spun, outside of the first component and has the greatest specific gravity, and wherein the third component is located, while the rotor is being spun, between the first and second components and has an intermediate specific gravity, and for causing the rotor's speed of rotation to be altered so as to cause the third component to mix with the first component, and for causing the flow-control arrangement to remove from the rotor a portion of the first component containing the second component.

2. A system of collecting platelets suspended in plasma, the system comprising:

a centrifuge rotor;

a flow-control arrangement which introduces whole blood into the centrifuge rotor and removes blood components from the centrifuge rotor;

a spinner which rotates the rotor at more than one speed;

a controller for causing the spinner to rotate the rotor at a first speed so as to separate the blood into a first component, a second component and a third component, wherein the first component is primarily plasma, wherein the second component is located, while the rotor is being spun, outside of the first component and is primarily red blood cells, and wherein the third component is

located, while the rotor is being spun, between the first and second components and includes platelets, and for causing the rotor's speed of rotation to be altered so as to cause the third component to mix with the first component, and for causing the flow-control arrangement to remove from the rotor a portion of the plasma containing platelets.

3. The system according to claim 2, wherein the controller causes the flow-control arrangement to remove some of the first component before the third component is mixed with the first component.

4. The system according to claim 3, further including a plasma-volume determination sensor in communication with the controller, wherein the plasma-volume determination sensor determines the volume of the first component in the rotor, and wherein the controller removes a portion of the first component based on the determined volume of the first component.

5. The system according to claim 2, wherein the centrifuge rotor has a variable total volume.

6. The system according to claim 5, wherein the centrifuge rotor is provided with a flexible diaphragm which defines the volume of the rotor.

7. The system according to claim 6, further including a pump which varies air pressure adjacent the flexible diaphragm so as to vary the total volume of the centrifuge rotor.

8. The system according to claim 7, wherein the centrifuge rotor is provided with a fixed portion, a rotatable portion and a rotary seal providing a seal between the fixed and rotatable portions.

9. A system of collecting platelets suspended in plasma, the system comprising:

a centrifuge rotor;

means for introducing whole blood into the centrifuge rotor and removing blood components from the centrifuge rotor;

means for (i) spinning the rotor at a first speed so as to separate the blood into a first component, a second component and a third component, wherein the first component is primarily plasma, wherein the second component is located, while the rotor is being spun, outside of the first component and is primarily red blood cells, and wherein the third component is located, while the rotor is being spun, between the first and second components and includes platelets, and (ii) for altering the rotor's speed of rotation so as to cause the third component to mix with the first component.

10. The system according to claim 9, further including a controller for causing the introducing means to remove from the rotor a portion of the first component containing platelets before the rotor's speed of rotation is altered.

11. The system according to claim 10, further including means for determining how much plasma should be removed from the rotor before the rotor's speed is altered.

12. A system for collecting platelets from whole blood, the method comprising:

a disposable set having

an inlet,

a platelet container,

a centrifuge rotor, and

tubing connecting the inlet, the platelet container and the rotor;

a control unit having

a spinner in which the rotor may be held and spun, and

a controller for causing the spinner to rotate the rotor so as to separate the whole blood into a first component, a second component and a third component, wherein the first component is primarily plasma, wherein the second component is located, while the rotor is being spun, outside of the first component and is primarily red blood cells, and wherein the third component is located, while the rotor is being spun, between the first and second components and includes platelets, and then altering the rotor's speed of rotation so as to cause the third component to mix with the first component.

13. The system according to claim 12, wherein the control unit further includes a flow-control arrangement, which urges a mixture of the first and third components out of the rotor, while the rotor is still spinning.

14. The system according to claim 12, wherein the flow-control arrangement causes a portion of the first component to be urged from the rotor before the third component is mixed with the first component.

15. The system according to claim 12, wherein the centrifuge rotor has a variable total volume.

16. A method of collecting platelets, the method comprising the steps of:

introducing whole blood into a centrifuge rotor;

spinning the rotor at a first speed so as to separate the blood into a first component, a second component and a third component, wherein the first component is primarily plasma, wherein the second component is located, while the rotor is being spun, outside of the first component and is primarily red blood cells, and wherein the third component is located, while the rotor is being spun, between the first and second components and includes platelets;

changing the rotor's speed of rotation so as to cause the third component to mix with the first component; and

removing from the rotor a portion of the plasma containing platelets.

17. The method according to claim 16, further including the step of removing a portion of the plasma from the rotor before the rotor's speed is changed.

18. A method of collecting platelets from whole blood, the method comprising:

providing a disposable set having an inlet, a platelet container, a centrifuge rotor, and tubing connecting the inlet, the platelet container and the rotor;

providing a control unit having a spinner in which the rotor may be held;

placing the rotor in the spinner;

drawing whole blood through the inlet;

directing the whole blood from the inlet through the tubing to the rotor;

causing the spinner to rotate the rotor so as to separate the whole blood into a first component, a second component and a third component, wherein the first component is primarily plasma, wherein the second component is located, while the rotor is being spun, outside of the first component and is primarily red blood cells, and wherein the third component is located, while the rotor is being spun, between the first and second components and includes platelets;

altering the rotor's speed of rotation so as to cause the third component to mix with the first component; and

urging a mixture of the first and second components out of the rotor, while the rotor is still spinning.

19. The method according to claim 18, wherein a portion of the first component is urged from the rotor before the third component is mixed with the first component.

20. The method according to claim 19, wherein the centrifuge rotor has a variable total volume.

21. The method according to claim 20, wherein whole blood is drawn through the inlet and directed to the rotor while the rotor is mounted in the spinner.

22. The method according to claim 21, wherein the centrifuge rotor is provided with a fixed portion, a rotatable portion and a rotary seal providing a seal between the fixed and rotatable portions, and the tubing is connected to the rotor's fixed portion.

23. The method according to claim 22, wherein the control unit varies the volume of the centrifuge rotor.

24. The method according to claim 23, wherein the centrifuge rotor is provided with a flexible diaphragm which defines the volume of the rotor, and the control unit is provided with means for varying air pressure adjacent the flexible diaphragm so as to vary the total volume of the centrifuge rotor.

25. The method according to claim 20, wherein the centrifuge rotor is provided with a fixed portion, a rotatable portion and a rotary seal providing a seal between the fixed and rotatable portions, and the tubing is connected to the rotor's fixed portion.

26. The method according to claim 19, wherein the disposable set includes a plasma-storage container and an RBC container, and wherein the method further includes the step of directing a portion of the first component to the plasma-storage container and the third component to the RBC container.

27. The method according to claim 19, wherein the disposable set includes return means, and wherein the method further includes the step of directing at least one of the first and second components back to the donor through the return means.

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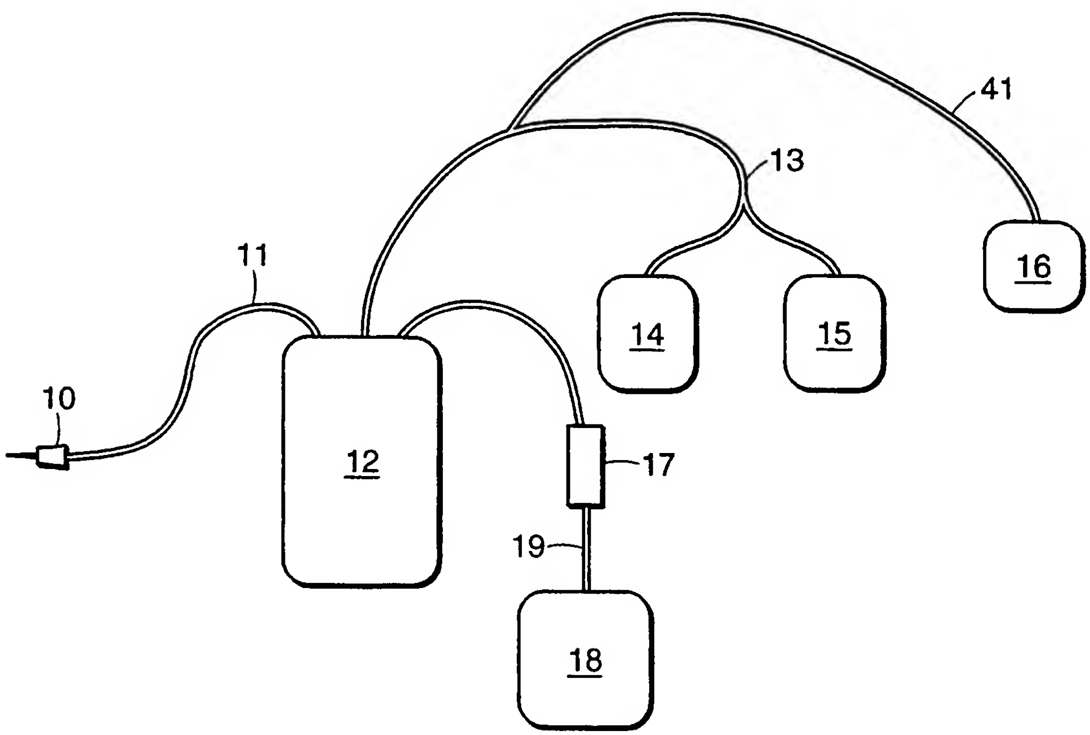


FIG. 1

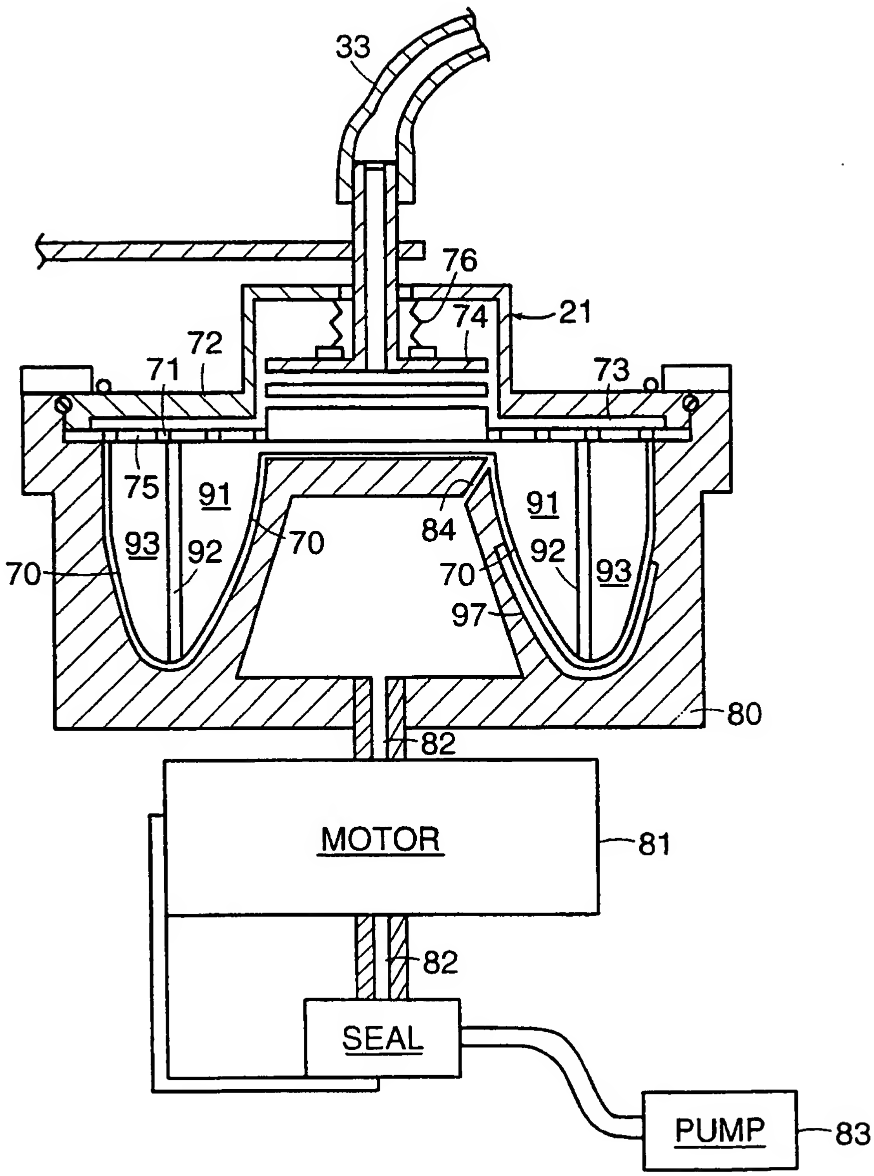
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FIG. 2

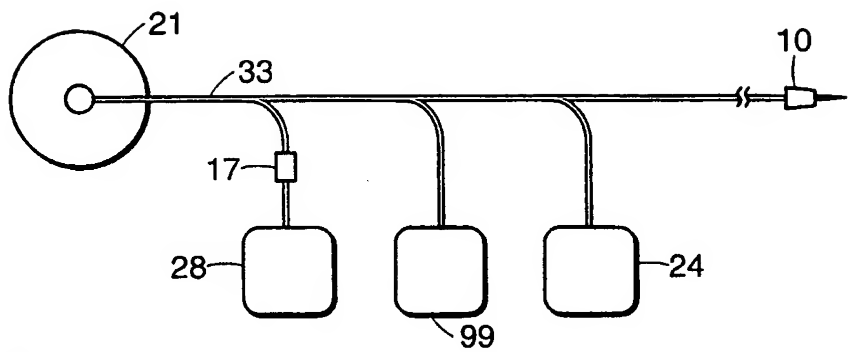
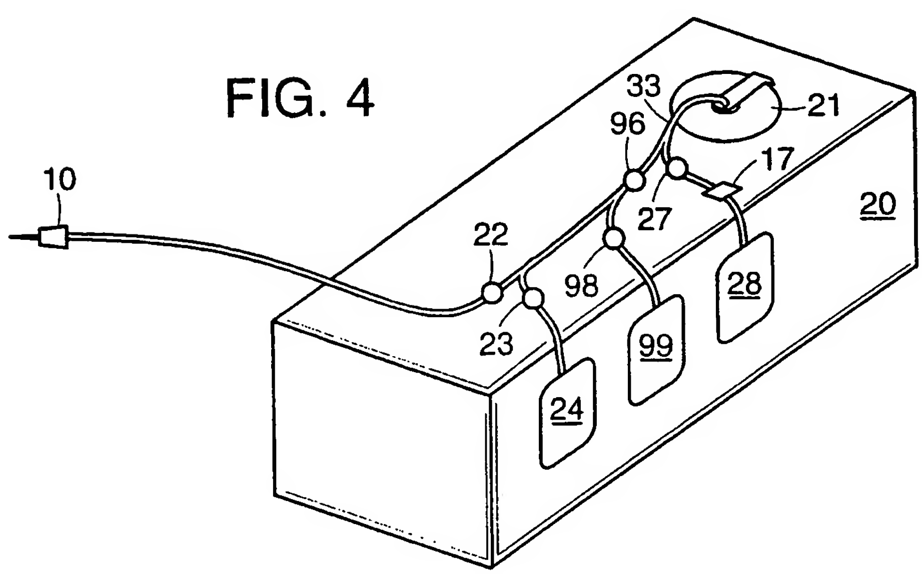



FIG. 3

FIG. 4



# INTERNATIONAL SERCH REPORT

Inte onal Application No
PCT/US 00/06561

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61M1/36 A61M1/02 B04B13/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M B04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5 733 253 A (POWERS EDWARD T ET AL)<br>31 March 1998 (1998-03-31)<br>cited in the application<br>the whole document<br>in particular see:<br>column 7, line 23 - line 45<br>column 11, line 56 -column 12, line 54 | 1,2,<br>5-10,12,<br>15 |
| A | column 12, line 39 - line 43 | 11 |
| A | column 21, line 9 -column 22, line 14<br>figure 3<br>--- | 16,18 |
| A | WO 96 33023 A (COBE LAB)<br>24 October 1996 (1996-10-24)<br>page 27, paragraphs 2,4; figure 5<br>---<br>-/-- | 1,2,9,<br>12,16,18 |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Lakkis, A |

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